## REMARKS

Claims 18-44 and claims 47-52 are pending in the present application. In the Office Action mailed May 25, 2006, claims 18-50 stand rejected under 35 U.S.C. § 112, first paragraph; claims 19, 27, and 51 stand rejected under 35 U.S.C. § 112, second paragraph; and claims 18-52 stand rejected under 35 U.S.C. § 103(a).

Applicants propose to amend claims 19 and 27 to delete non-fat soluble vitamins as suggested by the Examiner. Applicants propose to amend claim 51 to comply with matters of form. Applicants also propose to amend claims 18 and 29 as set forth herein. All amendments are made without prejudice or disclaimer.

The Applicants address the rejections as follows:

A. Rejection of claims 18-50 under 35 U.S.C. § 112, first paragraph

Claims 18-50 stand rejected under 35 U.S.C. § 112, first paragraph, for assertedly lacking enablement and for assertedly not complying with the written description requirement. Specifically, it is asserted that the scope of enablement only extends to tocopherols. Applicants respectfully traverse the rejections as set forth herein.

Applicants request clarification of the enablement rejection of independent claim 29 and the claims depending therefrom, as well as claim 20, claim 24, claim 33, claim 37, claim 41, and claim 51. The Final Office Action indicates that the specification is

enabling for vitamin E compositions and indicates that "the examples indicate the use of tocopherols" and that "the specification, which is only 7 pages, gives examples containing tocopherols." See, Final Office Action, page 2. Independent claim 29 is directed towards "liquid mixed tocopherols" and, thus, appears to be directed towards what the Final Office Action indicates is enabled. Further, each of dependent claim 20, claim 24, claim 33, claim 37, and claim 41 are directed towards liquid mixed tocopherols, and dependent claim 51 is directed towards a tocopherols which all appear to be enabled according to the statements in the Final Office Action.

Turning to the enablement rejection of the remaining claims including independent claims 18, 22, and 26, the *prima facie* burden is on the USPTO to demonstrate that the claims are not enabled under 35 U.S.C. § 112 (MPEP § 2164.04). Pursuant to MPEP § 2164.04, in order to make a rejection, the Patent Office has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (Examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, *unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.*

The fourth paragraph of the Detailed Description of the specification states:

> The vitamin-containing powders of the present invention may contain as their active vitamin ingredient any suitable vitamin, including an oil-soluble vitamin or mixture thereof, a water-soluble vitamin or mixture thereof, or mixtures of water and fat soluble vitamins.... In the present invention, the above and below described methods and compositions provide use of fat and/or water soluble vitamins comprising at least one vitamin selected from the group consisting of: vitamin A, vitamin D, vitamin, E, vitamin K, vitamin C, vitamin B1, vitamin B2, vitamin B6, vitamin B12, folic acid, biotin, inositol, beta carotene, vitamin B3, and vitamin B5, and mixtures thereof. Preferably, said vitamin comprises a mixed tocopherol composition....

The above statement from the specification, combined with the representative examples of embodiments of the specification, together teach one of ordinary skill in the art the manner and process of making and using the subject matter of claims 18-44 and 47-50. Independent claims 18 and 26 are each directed towards, *inter alia*, a composition including at least one fat soluble vitamin, while independent claim 22 is directed towards a composition including, *inter alia*, at least one vitamin. Consequently, the *prima facie* case has not been met by the Patent Office, and Applicants respectfully request withdrawal of the enablement rejections of claims 18-44 and 47-50.

The Declaration of Charles A. Morris filed with the Office Action Response of March 6, 2006 further overcomes the enablement rejections. Specifically, page 2, paragraph 8 of the Declaration, in conjunction with attached Exhibit B, provides substantial evidence that a stable dry form of vitamin $D_3$ oil can be produced in accordance with the teachings of the specification. As stated in the MPEP § 2164.05, "[t]his does not preclude applicant from providing a declaration after the filing date which demonstrates that the claimed invention works." Thus, the as-filed specification in

conjunction with the Declaration shows one of ordinary skill in the art would be able to make and use the compositions of independent claims 18, 22, and 26 since the Applicants have shown that both mixed tocopherols (i.e., a fat soluble vitamin) and vitamin $D_3$ oil (i.e., a fat soluble vitamin) can be produced.

As stated in MPEP § 2164.02, "for a claimed genus, representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art (in view of level of skill, state of the art and the information in the specification) would expect the claimed genus could be used in that manner without undue experimentation. Proof of enablement will be required for other members of the claimed genus **only** where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation" [emphasis added]. The Declaration serves as substantial evidence that the specification enables the making and use of the subject matter of claims 18-44 and 47-50 without undue experimentation by demonstrating that vitamin $D_3$ oil can be used to produce a free-flowing vitamin powder, which is in addition to the liquid tocopherols enabled by the specification. Thus, the genus "vitamins", solid or liquid, in claims 18-44 and 47-50 are enabled.

The Examiner must acknowledge as true the evidence presented in this Declaration, "unless the evidence is insufficient to overcome the rejection." M.P.E.P. § 716.01. If the rejection is maintained then, "the examiner must specifically explain why [emphasis added] the evidence is insufficient. General statements such as ... 'the evidence is not commensurate with the scope of the claims' without an explanation supporting such findings are insufficient." *Id.* The Declaration states on page 2,

paragraph 8, that the "stable dry form of vitamin $D_3$ oil exhibit[s] free flowing characteristics similar to those vitamin E compositions set forth in the specification." The Declaration also establishes the free-flowing characteristics, noting that it "blended well." *Id.,* Exhibit B. The Examiner merely contradicts this statement, but does not produce any evidence to the contrary. Thus, because no rebuttal evidence has been presented by the Examiner, the evidence of the record supports the enablement of claims 18-44 and 47-50. Accordingly, Applicants respectfully request reconsideration and withdrawal of the enablement rejections of claims 18-44 and 47-50.

The Examiner asserts that compounds comprising the genus "vitamins" have different chemical structures and characteristics and different chemical stabilities, and assumes that these differences would result in different free-flowing characteristics of the mixture. As stated in the Declaration, those of skill in the art understand that these characteristics and structures would not affect the free-flowing characteristics of the compositions of claims 18-44 and 47-52. As previously set forth herein, "general statements...without an explanation supporting such findings [by the Examiner] are insufficient." M.P.E.P. § 716.01. Thus, no evidence has been presented by the Examiner that the chemical characteristics and structures will have any impact on the free-flowing characteristics of the mixture. Therefore, since no evidence supporting the Examiner's conclusions has been presented and the Applicants have provided substantial evidence of how to make and use the composition of claims 18-50, withdrawal of the enablement rejections of claims 18-50 is respectfully requested.

B. Rejection of claims 19, 27 and 51 under 35 U.S.C. § 112, second paragraph

Claims 19 and 27 stand rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner objects to the inclusion of the water-soluble vitamin C and various B vitamins in the claims which depend from claims limited to fat soluble vitamins. Although Applicants believe that all vitamins are enabled, to expedite prosecution, claims 19 and 27 have been amended to include those vitamin species that are fat-soluble.

Claim 51 stands rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite because the scope of the claim was thought to be unclear. The claim has been amended such that the fat soluble vitamin comprises tocopherols.

Accordingly, reconsideration and withdrawal of the indefiniteness rejections of claims 19, 27, and 51 are respectfully requested.

C. Rejection of claims 18-50 under 35 U.S.C. § 103(a)

Claims 18-50 are rejected under 35 U.S.C. § 103(a) as being assertedly obvious in light of Schmidt et al. (U.S. Patent No. 4,486,435; hereinafter the '435 patent) in combination with Schmidt (U.S. Patent No. 4,603,143; hereinafter the '143 patent).

A *prima facie* case of obviousness cannot be established since the cited references do not alone, or in combination, teach or suggest each and every element of any of claims 18-44 or 47-52. For instance, independent claim 18 is directed towards a composition comprising, *inter alia*, 65 to 80 weight percent of at least one fat soluble vitamin, and independent claim 29 is directed towards a product having 65 to 80 weight percent of liquid mixed tocopherols. The cited references disclose ranges of vitamins

that fall outside the elements of independent claims 18 and 29. For instance, the '143 patent discloses about 40 weight percent to about 60 weight percent (see column 3, lines 11-12), and the '435 patent discloses about 45 weight percent to about 60 weight percent (see column 4, lines 54-56).

Additionally, independent claims 18, 22, 26, and 29 each include an element of silica having a particle size of between 40 and 50 microns. The cited references do not alone, or in combination, teach or suggest silica with such a particle size. For instance, the '143 patent discloses a particular criticality to silica particles with minimum sizes of 300 microns (see column 2, lines 14-20). Further, the '435 patent discloses silica particle sizes of about 0.01 microns to about 0.04 microns (see column 3, lines 33-37). Thus, neither the '143 patent nor the '435 patent teach or suggest the silica with particle sizes as recited in all of independent claims 18, 22, 26, and 29. To establish *prima facie* obviousness, **all** claim elements must be taught or suggested by the combination of prior art. MPEP § 2143.03. Since, the cited references do not teach or suggest each and every element of any of claims 18-44 or 47-52, a *prima facie* case of obviousness cannot be established.

Furthermore, there is no teaching, suggestion, or motivation to combine the cited references. Specifically, it is stated in the '143 patent that "the various processes of the prior art which involve the use of water and emulsifiers, such as gelatin and starch, and spray-drying techniques are unnecessary to the process of the invention." U.S. Patent No. 4,603,143, column 2, lines 39-42. Further, the '435 patent explicitly teaches a spray-drying process and a spray-dried composition (see claims 1 and 6, and column 1,

lines 40-60). Consequently, one of ordinary skill in the art would not be motivated to use "unnecessary" components absent some teaching to the contrary.

If anything, the cited references teach away from each other. As stated in *In re Gurley*, 27 F. 3d 551 (Fed. Cir. 1993), "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would lead in a direction divergent from the path that was taken by the applicant." The fact that the '143 patent specifically mentions the lack of utility of these components leads one of ordinary skill in the art away from using such components. As such, the '143 patent specifically teaches away from using the components of the '435 patent. Thus, the Applicants respectfully request withdrawal of the obviousness rejections of claims 18-44 or 47-52.

In addition, when considered in its entirety, the '435 patent teaches the use of cornstarch but only as an encapsulating agent/binder (column 2, lines 35-36) and/or as a water-insoluble carrier (column 3, line 7) in combination with ultrafine aerosolized silica for encapsulating particles of vitamin, binder, and carrier during a spray-drying process (column 3, lines 12-15). Moreover, the '435 patent teaches that such silica particles must be "ultrafine" to encapsulate the vitamin, binder, and carrier. Specifically, column 3, lines 12-15 of the '435 patent states "of **critical** importance in the preparation of the vitamin powders of the invention [by spray-drying] is the utilization of ultrafine particle size materials which are capable of coating the partially dried, encapsulated vitamin component." Given these key points, one of ordinary skill in the art would readily recognize that the use of silica that is not ultrafine would result in ineffective spray-dried silica coatings rendering in the modification of the teachings the '435 patent

unsatisfactory for its intended purpose. Pursuant to MPEP § 2143.01(VI), "if proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984). Accordingly, the '435 patent cannot be modified to act as a reference that would render obvious the claimed compositions.

The term "ultrafine" is defined as silica having a particle size of about 0.01 microns to about 0.04 microns. See, the '435 patent at column 3, lines 33-36. In contrast, the particle size (about 40 microns to 50 microns) recited as an element, directly or indirectly as a dependent claim, of each of claims 18-44 or 47-52 is ≥3000 times larger than that taught in the '435 patent. Indeed, the small particles of silica form a spray-dried coating. Thus, the silica encapsulated aggregates of the '435 patent are clearly distinguishable as conventional spray-dried particle aggregates that lack the disclosed advantages of the compositions or products of claims 18-50 (see the specification, paragraph [0004]). Thus, neither reference teaches nor suggests a free-flowing composition where both starch and silica of the size ranges recited in claims 18-44 or 47-52 are combined.

Thus, a *prima facie* case of obviousness cannot be sustained for at least the reasons that there is no suggestion or motivation to modify the references, the references teach away from the claimed compositions, and the combination of the cited references does not teach or suggest each and every element of any one claims 18-44 or 47-52. For at least the reasons discussed above, reconsideration and withdrawal of

the rejections of claims 18-44 and 47-52 are requested. Claims 18-44 and 47-52 define over the prior art of record and are in proper form for allowance.

## ENTRY OF AMENDMENTS

The proposed amendments to claims 18, 19, 27, 29, and 51 should be entered because the amendments are supported by the as-filed specification, do not add any new matter to the application, and do not require a further search. The proposed amendments to claims 18, 29, and 51 merely remove a few words. The proposed amendments to claims 19 and 27 comply with the Examiner's suggestions. Further, since the proposed amendments to the claims are not anticipated or rendered obvious by the cited references, the amendments should be entered since they place the application in condition for allowance. Finally, if the Examiner determines that the amendments do not place the application in condition for allowance, entry is respectfully requested since they certainly remove issues for appeal.

If the undersigned can be of assistance to the Examiner regarding any of the above, please contact the undersigned at the number set forth below.

Respectfully submitted,

7/25/06
Date

C. Allen Black
Reg. No. 53,835
Customer No. 41,835

KIRKPATRICK & LOCKHART Nicholson Graham LLP

Henry W. Oliver Building
535 Smithfield Street
Pittsburgh, Pennsylvania 15222

Telephone: (412) 355-6319
Facsimile: (412) 355-6501